REMARKS/ARGUMENTS

Responsive to the June 8, 2009 Final Office Action, claims 1-13, 16-22, and 24-26 have been canceled and claims 14 and 15 have been withdrawn. Claims 23, 27 and 28 have been amended. Accordingly, claims 23 and 27-35 remain pending for prosecution with claim 27 being independent and all other claims depending therefrom.

I. CLAIM OBJECTIONS

The Office Action objected to claims 17 and 27 for the following informalities: claim 17, "affect" in line 1 should be "effect" and in claims 17 and 27, "a muzzle" in line 3 should be "the muzzle." Claim 17 has been canceled rendering the objections to claim 17 moot. Claim 27 has been amended to reflect the suggested revision; therefore, Applicant respectfully requests the withdrawal of the objection to claim 27.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 112

Claims 17-35 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant has canceled claims 17-22 and 24-26; thus, rendering this rejection moot as to these claims. Further, Applicant has revised the preamble to claim 27 to clarify that the method for treating a livestock animal is to achieve a positive effect on the health of "the livestock animal." Applicant therefore respectfully requests reconsideration and withdrawal of the 35 U.S.C. § 112 rejection as to claims 23 and 27-35.

III. CLAIM REJECTIONS UNDER 35 U.S.C. § 103

A. Obviousness

When determining the question of obviousness, underlying factual questions are presented which include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art at the time of the invention; (3) objective evidence of nonobviousness; and (4) the differences between the prior art and the claimed subject matter. Graham v. John Deere Co., 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). Moreover, with regard to the last prong of the *Graham* inquiry, "[t]o determine whether there was an apparent reason to combine the known elements in the way a patent claims, it will often be necessary to look to interrelated teachings of multiple patents; to the effects of demands known to the design community or present in the marketplace; and to the background knowledge possessed by a person having ordinary skill in the art. To facilitate review, this analysis should be made explicit." KSR International v. Teleflex Inc., 127 U.S. 1727 (2007).

Applicant does not contest that the references that have been cited and relied on by the Examiner have at least marginal pertinence to the particular problem(s) solved by the present invention in that the references disclose methods for treating or vaccinating animals. Stratoflex, Inc. v. Aeroquip Corp., 713 F.2d 1530, 1535, 218 USPQ 8781, 8786 (Fed. Cir. 1983).

The person of ordinary skill in the art is a hypothetical person who is presumed to know the relevant prior art. Custom Accessories, Inc. v. Jeffrey-Allan Indus., Inc., 807 F.2d 955, 962, 1 USPQ2d 1196, 1201 (Fed. Cir. 1986). The level of ordinary skill in the art of veterinary compositions and methods for treating animals may be determined by looking to the references of record. In re GPAC, Inc., 57 F.3d 1573, 35 USPQ2d 1116 (Fed. Cir. 1995). The references of record in this case reveal that a moderate level of sophistication in the veterinary arts is

associated with one of ordinary skill. Thus, Applicant submits that, as substantiated by the cited references, those with at least a bachelor's degree in chemistry or biochemistry or substantial experience in the veterinary industry or the like would most likely be a person with ordinary skill in this field of endeavor.

With respect to objective evidence of nonobviousness, Applicant re-asserts that the record supports the conclusion that there are long-felt but unsolved needs met by the present invention. The present invention is directed to the particular problem of providing a method for treating livestock with a veterinary composition that avoids the use of needles, administers the composition to the animal's mucosal membranes, avoids close physical contact with the animal, and provides a visual indicator of vaccination. The present invention does not require a handler to have to fight with the animal's head thereby minimizing stress on the animal. The reduced degree of contact between man and animal provided by the present invention greatly reduces risk of injury to both. Additional benefits of the present invention over the prior art include avoiding the insertion of needles into edible tissues thereby avoiding site reactions which may result in the loss of saleable tissues due to injection site lesions showing up in the final food product.

The present invention also uses the natural route of infection in order to lead to the best possible and most appropriate immune response while minimizing the physical contact between man and animal. The present invention is also cost effective in that it requires minimum reformulation and does not require any new technology for use in connection with respiratory viruses and/or attenuated bacteria. Finally, the present invention allows handlers of large groups of livestock animals to visually identify animals that have already been administered the prophylactic composition. The post-application identifier increases administration efficiency and prevents an animal from being given two doses of the prophylactic composition and also allows

the handlers to visually identify animals that have not been administered the prophylactic composition. In summary, the present application is directed to a method of treating livestock that includes applying an effective dose of a veterinary composition directly to the muzzle of animal wherein the animal distributes the medicine into its mucosal membranes with its tongue and the method also includes a post-application identifier. These features represent a solution to long felt needs in the art that could not be met by the known prior art.

Finally, prima facie obviousness requires that there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references. This motivation-suggestion-teaching test informs the Graham analysis. "To reach a non-hindsight driven conclusion as to whether a person having ordinary skill in the art at the time of the invention would have viewed the subject matter as a whole to have been obvious in view of multiple references," there must be "some rationale, articulation, or reasoned basis to explain why the conclusion of obviousness is correct." In re Kahn, (Fed. Cir. 2006). The KSR International decision by the Supreme Court has not eliminated the motivation-suggestion-teaching test to determine whether prior art references have been properly combined. Rather, in addition to the motivation-suggestion-teaching test, the Court discussed that combinations of known technology that are "expected" may not be patentable. Stated in the affirmative, therefore, combinations are nonobvious and patentable if unexpected. In the present application, no single prior art reference nor any combination thereof meets the claimed limitations or provides an expectation of Applicant's invention.

B. Rejection of Claims 17, 18, 21, 22, 24, 26, 27, 28, 31, 32, 33 and 35 over Chu in view of Gallili.

Claims 17, 18, 21, 22, 24, 26, 27, 28, 31, 32, 33 and 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. (US 2002/0025325) in view of Gallili et al. (US 6,541,001 B1). For the following reasons, Applicant respectfully requests reconsideration and withdrawal of these rejections.

The Office Action asserts that Chu "teaches a method of treating livestock . . . to protect them against disease (achieve positive effect on the health of the animal) comprising administering a veterinary prophylactic agent . . . which comprising [sic] an effective dose of a vaccine comprising formulating the vaccine into drinking water/vaccine formulation when it goes to drink water." (Office Action page 6). As support for the §103(a) obviousness finding, the Office Action asserts that, "by the animal drinking the water/vaccine mix from a bucket or trough the water/vaccine mix is applied directly to the muzzle . . . when the animal sticks its head into the bucket or trough and when said animals inherently licks it muzzle with its tongue, they will distribute the water/vaccine mix into their oral and nasal cavity." (Office Action page 6).

While the Office Action admits that Chu does not disclose a post-application identifier, the Office Action asserts "Gallili et al teaches vaccines for livestock . . . in tablet form comprising . . . post identification such as colorants (light visible dyes) to help identify types of vaccine formulation that can be dissolved in a diluent and applied as a whole body spray."

Based on these assertions, the Office Action presents the following obviousness conclusions:

(1) "[i]t would have been prima facie obvious to one of ordinary skill in the art a the time the instant invention was made to substitute, in the method of Chu et al., the vaccine of Chu et al.

with the vaccine of Gallili et al. as set forth above because Gallili et al teaches a vaccine agent that can also be used to achieve a positive effect on the health of livestock animals . . . and also because Gallili et al. teaches that its vaccine agent can also be dissolved and administered via drinking water" and this "modification of Chu et al. results in the instant invention with a reasonable expectation of success;"

(2) "[a]lternatively, it would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to add a light visible dye to the vaccine of Chu et al because Gallili et al teaches that colorants (light visible dyes) to help identify types of vaccine formulation;" and

(3) "[i]t would have been prima facie obvious . . . at the time the instant invention was made that the vaccine of Chu and Gallili et al as combined above can be applied as whole body spraying involving spraying the diluted vaccine to all areas of the livestock animal including the face which comprises the muzzle (whole body spray) and due to the inherent natural licking behavior of cattle and other large farm animals the sprayed vaccine is distributed into the oral and nasal cavities to contact the oral and nasal mucosa when said animal eventually lick the muzzle with its tongue." (Office Action page 7).

Applicant respectfully traverses these assertions that the Chu and Gallili references, alone or as combined, teach or suggest all of Applicant's claim limitations or that the claimed limitations of the present invention are expected when Chu and Gallili are combined. Applicant's claimed invention that is directed to a method of administration of the prophylactic compositions is not rendered obvious by the combination of Chu and Gallili for the reasons discussed hereinbelow.

1. Chu et al. does not teach directly applying an effective dose to the muzzle of a livestock animal wherein the effective dose is distributed to the nasal and oral mucosa.

Chu does not teach directly applying an effective dose of prophylactic composition to the muzzle of an animal wherein the effective dose will be distributed to the nasal and oral mucosa by the animal's tongue. Chu exclusively teaches that each animal will self-administer the effective dose of the vaccine by drinking water that contains the vaccine. The effective dose of the vaccine is determined by calculating how much water, on average, an animal will drink during the vaccination period. (Chu ¶ 0086). Chu does not teach directly applying an effective dose to the animal's muzzle. Chu does not teach that an animal indirectly applies an effective dose to its own muzzle. Chu's method is exclusively focused on an indirect method of administering a vaccine wherein the animal self-administers the vaccine through drinking water that contains the vaccine. The animal ingests the effective dose and the effective dose of the vaccine is absorbed into the animal through the animal's digestive system. Chu's effective dose of the vaccine is exclusively taught to be contained in the average amount of water consumed by the animals and not applied to the muzzle and then distributed to the animal's oral and nasal mucosa.

Chu does not teach that the animal absorbs the effective dose or any of the vaccine through the nasal or oral mucosa. Chu does not teach or suggest that the vaccine contained in the water can or will be absorbed into the animal through the nasal or oral mucosa in lieu of the digestive tract. Chu's disclosure fails to teach, suggest or motivate a person skilled in the art to directly apply an effective dose on an animal's muzzle. Chu's disclosure also fails to teach,

suggest, or motivate a person skilled in the art to introduce a vaccine into the animal through the nasal or oral mucosa.

2. Chu teaches away from the claimed limitations of the present invention.

Chu clearly teaches away from the present invention's claimed limitation of directly applying an effective dose of a prophylactic composition to the muzzle of a livestock animal. Chu teaches that "efficacious vaccine administered to groups of animals through drinking water (mass administration) . . . would be of great benefit to producers by saving labor costs [associated with individual administration] as well as avoiding stress and damage to the meat caused by needles." (Chu ¶ 0006). Inherently, Chu's disclosure requires that a portion of the livestock will not receive the effective dose as there is statistical certainty that some animals will not consume the average amount of water during the administration period as an average necessarily includes consumption above and below the average. Chu's promotion of its method of indirect mass administration of the vaccine through drinking water teaches away from individually and directly applying the prophylactic composition to an animal's muzzle as claimed in the present invention. Directly applying an effective dose may require a higher degree of labor cost, but virtually ensures that each animal is exposed to an effective dose of the vaccine. Chu teaches that the savings in labor and reducing the stress on animals resulting from Chu's indirect "mass administration" method outweighs the statistical certainty of Chu's method that at least a portion of the animals will not receive the effective dose and necessarily teaches away from direct application of the effective dose on the muzzle.

Further, Chu teaches away from the animal receiving the effective dose through the nasal and oral mucosa by exclusively promoting the benefit of Chu's method of mass administering

the vaccine through drinking water and absorption through the digestive system. Even if some water containing the vaccine remained on the muzzle of a livestock animal after watering, there would be an insufficient amount of the vaccine present to constitute an "effective dose." The effective dose in Chu is determined by a concentration of vaccine that will be present in the large volume of water consumed by an animal in a vaccination period—2.5 to 12 gal/day for livestock animals. (Chu ¶ 0008). The effective dose taught by Chu would involve a substantially greater volume of liquid than could be applied to an animal's muzzle or distributed from the muzzle to the animal's nasal an oral mucosa by the animal's tongue during the administration period. Thus, Chu's method teaches away from direct application of effective dose to an animal's muzzle wherein the effective dose is distributed to oral or nasal mucosa by the animal's tongue.

3. Gallili does not teach, suggest, or motivate a person skilled in the art to use a post-application identifier.

Gallili does not disclose a post-application identifier. Gallili teaches "[c]olorants are added to help identify types of vaccine formulations such as in the form of tablets for aesthetic and functional purposes" (col. 11, line 17-22) and does not teach using colorant to identify a livestock animal that has already been administered a prophylactic composition. Gallili's sole suggestion and motivation for using colorant is presented in col. 21, lines 22-28, "coloring the various different types of vaccines (or color coding) . . . in different contrasting colors is useful against mistakes that have been made by farmers who have vaccinated their poultry flocks with a different type vaccine than the one intended, thereby exposing their unprotected flocks against the disease which they had actually intended to immunize." Gallili's teaching of the use of color is exclusively pre-application and is limited to identifying the particular type of vaccine being used. Further, there is no teaching, suggestion or motivation that the concentration of dye

present after Gallili's tablet is dissolved in water is sufficient to be used as a post-application identifier.

Moreover, Gallili does not teach, suggest or motivate a person in the art to use a colorant as a post-application identifier. Gallili's sole teaching, suggestion and motivation for the use of color in the tablets is to help the farmer identify the correct vaccine prior to administration of the vaccine to help prevent the farmer from damaging the poultry by administering the wrong composition. Gallili has no teaching, suggestion that the colorant has any useful applications subsequent to the administration of the vaccine. A person skilled in the art of the present invention is not attributed extensive knowledge in the art of coloring dyes and would not likely be attributed more knowledge of dyes used with vaccines than disclosed in Gallili. Therefore, Gallili provides no teaching, suggestion, motivation for a person skilled in the art to use the colorant that identifies tablets containing a particular vaccine as a post-application identifier. Further, the post-application identifier of the present invention would certainly be an unexpected result of the combination of the Chu and Gallili when the only disclosure of a colorant consists of using the colorant to identify tablets containing a particular vaccine.

4. Gallili teaches away from applying an effective dose of prophylactic directly to the muzzle.

Gallili does not teach applying an effective dose of the prophylactic composition directly to the animal's muzzle. Gallili teaches that the effective dose of a prophylactic composition can be achieved using a whole body spray. (Col. 12, lines 56-59). This application method teaches away from directly applying an effective dose to the muzzle of the livestock animal. While some of the spray may hit the muzzle during the whole body spray, the effective dose is applied over the entire body - not the muzzle in particular. It is impossible, therefore, for the whole body

spray to deliver the effective dose to the animal's muzzle as concluded in the Office Action (page 7). Gallili does not teach, suggest or motivate a person skilled in the art to spray the prophylactic composition on the muzzle exclusively, and Gallili does not teach or suggest that the composition will be effective if it is distributed to the animal's oral or nasal mucosa. In fact, Gallili teaches away from the Applicant's claimed invention of direct application of an effective dose to the muzzle by teaching the use of a "whole body" spray as the effective administration method to apply the effective dose of vaccine.

5. There is no rationale, articulation, or reasoned basis presented to explain that the present invention is the expected result when a person of ordinary skill in the art combines the teachings of Chu and Gallili.

The combination of elements from the references Chu and Gallili as presented in the Office Action does not result in the present invention as claimed. There is no teaching, suggestion, or motivation in the references that would indicate the present invention would be an expected result of the combination of Chu and Gallili; therefore, the required components of a prima facie case of obviousness have not been satisfied.

In response to the Office Action's first and second conclusions of obviousness presented above, the combination of the cited Chu and Gallili teachings would result in the following: a trough full of water that contains a vaccine compound, wherein the desired vaccine has been identified by the color of a tablet containing the vaccine that is dissolved in the water; an animal self-administers the vaccine by drinking the water; and finally, the effective dose of vaccine would be absorbed into the animal through its digestive system. This combination clearly does not meet the following claimed limitations of the Applicant's invention: directly applying an effective dose of a prophylactic composition to the muzzle of the livestock animal, wherein the

livestock animal will distribute the composition directly to the oral and nasal mucosa with its tongue wherein the prophylactic composition is absorbed into the animal through the oral and nasal mucosa, and the prophylactic composition contains a prophylactic agent and a post-application identifier. Moreover, the Office Action fails to demonstrate that there is any teaching, suggestion, motivation for a person of ordinary skill in the art to reasonably modify the teachings of Chu and Gallili such that the present invention is the expected result of the combination of Chu and Gallili.

Finally, the Office Action's third alternative conclusion of obviousness—concluding the application of the diluted vaccine of Chu and Gallili as a whole body spray teaches applying an effective dose to the muzzle—also fails to establish a prima facie obviousness of directly applying an effective dose to the muzzle. The application of a vaccine effective dose as a whole body spray does not teach applying an effective dose of a vaccine directly to the muzzle or any other individual body part. The effective dose is necessarily applied over the entire surface area of the animal's body; therefore, even if some spray does hit the muzzle, an effective dose will not be directly applied to the muzzle and subsequently delivered to the oral or nasal mucosa. Applying the effective dose using a whole body spray teaches away from applying directly to the muzzle. Moreover, there is no teaching, suggestion or motivation in either reference promoting the application of an effective dose of the vaccine directly to the muzzle of a livestock animal.

Accordingly, Chu and Gallili, individually and in combination, fail to teach or suggest the combination asserted in the Office Action. Further, neither of the references teaches nor suggests all of the elements of independent Claim 27 and no resultant method could have been created from these references that would meet the limitations of these claims. Chu does not teach direct application of an effective dose of a prophylactic composition to the muzzle of a

livestock animal or that the effective dose of the prophylactic composition will be delivered to the nasal or oral mucosa by the animal's tongue. In fact, Chu teaches away from direct application of a vaccine to the animal. Moreover, Gillili's tablet only teaches enough colorant present in the vaccine tablet to identify the vaccine by color prior to dilution and application. Applying the effective dose of a vaccine by spraying the whole body does not teach, and effectively teaches away from, applying an effective dose solely on the muzzle. Therefore, one of ordinary skill in the art would not have arrived at Applicant's claimed invention because Applicant's invention would not be an expected result of the combination of these references since both references, individually and in combination, fail to meet all the limitations of the subject claims. Accordingly, Applicant's independent claim 27 and the claims depending therefrom are nonobvious.

C. Rejection of Claim 23 over Chu in view of Gallili, further in view of Emery et al.

Claim 23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. in view of Gallili et al., further in view of Emery et al. US 5,906,826. Per the arguments presented above in Section B, the combination of Chu and Gallili does not establish a prima facie case of obviousness for independent claim 27 or the claims depending therefrom. In addition, Chu, Gallili, and Emery et al (US 5,906,826), alone or in combination do not teach, suggest, or motivate the combination asserted in the Office Action. Emery may teach the use of additives in a prophylactic composition; however, Emery does not teach directly applying an effective dose of such composition to the muzzle of a livestock animal wherein the animal distributes the effective dose to the animal's oral and nasal mucosa with its tongue. Emery contains no

suggestion or motivation for such application, nor would a person of ordinary skill in the art expect the present invention when considering Chu, Gallili, or Emery whether alone or in combination. Therefore, claim 23 of the present invention is nonobvious.

D. Rejection of Claims 25 and 34 over Chu in view of Gallili, further in view of Demello et al.

Claims 25 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Chu et al. in view of Gallili et al., further in view of Demello et al. US 5,846,830. For the following reasons, Applicant respectfully requests reconsideration and withdrawal of this rejection. Applicant respectfully traverses the assertion that the Chu, Gallili and Demello references, when combined, teach or suggest all of Applicant's claim limitations or that the claimed limitations of the present invention is the expected result when Chu, Gallili and Demello are combined. Applicant's claimed invention is directed to a method of administration of a prophylactic composition and is not rendered obvious by the combination of Chu, Gallili and Demello for the reasons discussed hereinbelow.

Per the arguments presented above in Section B, the combination of Chu and Gallili does not establish a prima facie case of obviousness for independent claim 27 or the claims depending therefrom. Demello is compatible subject matter with the teachings of Chu and Gallili in that it teaches the UV dye is ingested by the animal in drinking water; however, Domello does not teach or suggest a person of skill in the art to use a UV dye or other non-visible dye as a post-application identifier on the exterior of an animal while administering a prophylactic compound. Further, Demello does not teach directly applying an effective dose of a prophylactic composition to the muzzle of a livestock animal wherein the animal distributes the effective dose

to the animal's oral and nasal mucosa with its tongue. Demello teaches mixing small amounts of fluorescein dye with the food and/or water of an animal six to ten hours before slaughtering and exposing the already slaughtered carcasses to UV light to detect the presence of feces or urine in the processed carcasses. Demello does not use UV marking to identify individual animals, but to detect the presence of feces or urine. There is no teaching, suggestion, or motivation in Demello to use the fluorescein dye for any other purpose, including individually identifying animals after application of prophylactic compositions.

Moreover, the asserted combination of Chu, Gallili and Demello would actually result in a vaccine and fluorescein dye dissolved in water in a trough wherein the animal consumes the vaccine and dye present in the water, and both are processed within the digestive system, wherein the presence of the dye can be detected in the feces and urine of the livestock animal. This combination of the cited references does not result in the present invention: an effective dose of the prophylactic composition being applied directly to muzzle, the effective dose being distributed to the nasal and oral mucosa by the animal's tongue, and that the individual animal can be identified after it has been administered the effective dose. Further, the Office Action fails to show any teaching or suggestion to modify the cited references such that the present invention would be the expected result of the combination of Chu, Gallili and Demello as asserted.

The present invention requires that animals that have been administered the prophylactic composition can be identified as such. Domello does not teach a method to identify the presence of the UV dye prior to the animal being slaughtered. Domello at most inherently discloses a UV dye that may be detected in the feces and urine of a live animal. Domello's disclosure teaches away from a post-application identifier is multiple reasons. First, Domello's disclosure does not

provide the benefit of the post-application identifier of the present invention because Domello does not teach that the UV dye is physically present and readily identifiable on the exterior of the animal. Second, the inherent delay between ingesting the dye and the purging of the animal's waste containing the dye does not allow for identification of a particular animal that has been recently administered the vaccine until the animal urinates or defecates.

Third, it is not reasonably practical to identify a particular animal in a group of livestock animals by identifying the presence of UV dye in their feces and urine. The only way to identify that an animal has been administered the vaccine would require a person to observe, monitor, and test the feces or urine at the exact time the waste is excreted by the particular animal under observation. If the monitoring is not carried out at the exact time of the waste is excreted, there is little chance of matching urine or feces samples already on the ground with a particular animal. In reality, it would take more labor to follow the animals around with a UV light to test for the presence of the dye in the waste to identify animals that have been administered the vaccine than it would to actually administer the vaccine with the present invention. The labor required to monitor animals in order to identify whether they have been administered the vaccine as taught in Demello teaches away from the asserted combination with Chu because Domello's teaching is grossly inefficient and would cancel, if not obliterate, the efficiency benefits of "mass administration" touted in the disclosure of Chu.

Thus, Demello's teaching of using UV identifier to identify the presence of feces or urine in a carcass teaches away from using the UV dye as a post-application identifier for a particular animal because Domello does not teach or suggest exterior application of the UV dye, the time lag between administration and the ability to verify presence of the UV dye does not allow for immediate post-application identification, the labor and process required to identify a particular

animal using Domello's teaching is not consistent with Chu's stated focus on efficiency of "mass administration," and, once defecation or urination occurs, there is little way to readily identify a particular animal by the deposited feces or urine. Domello does not teach, suggest, or motivate or provide a reasonable expectation of the present invention when combined with Chu and Gallili. Accordingly, Applicant's claim 34 is nonobvious.

E. Rejection of Claims 17, 18, 21, 22, 24, 26, 27, 28, 31, 32, 33 and 35 over Dowling in view of Gallili.

Claims 17, 18, 21, 22, 24, 26, 27, 28, 31, 32, 33 and 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Dowling et al. (US 6,177,082 B1) in view of Gallili et al. (US 6,541,001 B1). For the following reasons, Applicant respectfully requests reconsideration and withdrawal of these rejections.

The Office Action explains that Dowling "teaches a method of treating livestock . . . to protect them against influenza virus (achieve positive effect on the health of the animal) comprising a veterinary prophylactic agent . . . directly via nebulizer to the nose and mouth of animal (muzzle of the animal)." Further, the Office Action concludes that "the vaccine being applied on to the muzzle [by the nebulizer] the animal distributes the vaccine into the oral and nasal cavity when it engages in inherent natural licking of their muzzles with their tongues." Finally, after restating that Gallili teaches vaccines that can be applied as aerosol or nasal spray for livestock comprising colorant to help identify types of vaccine formulation, the Office Action concludes "it would have been prima facie obvious . . . to add a colorant to the vaccine of Dowling et al because Gallili teaches that colorants such as dyes help identify types of vaccine formulations." Applicant respectfully traverses the assertion that the Dowling and Gallili

references, when combined, teach or suggest all of Applicant's claim limitations or that the claimed limitations of the present invention are the expected result when Dowling and Gallili are combined. Applicant's claimed invention directed to a method of administration of prophylactic compositions to livestock animals is not rendered obvious by the combination of Dowling and Gallili for the reasons discussed hereinbelow.

1. Dowling et al. does not teach directly applying an effective dose to the muzzle of a livestock animal wherein the effective dose is distributed to the nasal and oral mucosa.

Dowling does not teach directly applying an effective dose of prophylactic composition to the muzzle of an animal wherein the effective dose will be delivered by the animal's tongue to the nasal and oral mucosa. It is well known in the art that a nebulizer is a device used to administer medication in the form of a mist that is inhaled into the lungs. Dowling teaches the effective dose of the influenza vaccine being inhaled as a mist by the animal into the respiratory system after an operator physically restrains a livestock animal's head and places a nebulizer over its nose and mouth. While the nebulizer device may be in proximate contact with the muzzle of an animal, the effective dose of Dowling's composition is exclusively inhaled into the animal's respiratory system and is not directly applied to the muzzle. Therefore, Dowling does not teach directly applying an effective dose of a prophylactic composition to the muzzle of an animal and certainly does not indicate a reliance on the animal's tongue to distribute the effective dose to the nasal and oral mucosa. Moreover, by teaching the use of a nebulizer, Dowling teaches intranasal administration of a vaccine and does not teach, suggest, or motivate to directly apply the effective dose of the prophylactic composition to the livestock animal's muzzle

wherein the effective dose is distributed to the nasal and oral mucosa by the animal's tongue as claimed in the present invention.

2. Dowling teaches away from the claimed limitations of the present invention.

Dowling clearly teaches away from the present invention's claimed limitation of directly applying an effective dose of a prophylactic composition to the muzzle of a livestock animal. Dowling teaches that intranasal administration "may be accomplished . . . by use of a nebulizer fitted over the nose and mouth of the animal to be vaccinated." (Col. 13, lines 30-39). Dowling teaches intranasal administration and not exterior administration to the muzzle as claimed in the present invention. Therefore, by solely promoting intranasal administration, Dowling actually teaches away from administering the vaccine to the exterior surface of the animal's muzzle. Moreover, placing a nebulizer over the nose and mouth of an animal does not teach directly applying the prophylactic composition to the muzzle. A nebulizer is a machine that performs and facilitates the intranasal administration of a vaccine and its implementation in Dowling teaches away from directly applying the vaccine to the animal's muzzle.

Further, Dowling's teaching of the use of a nebulizer requires close contact between the handler and the animal. The livestock animal's head must be restrained while affixing the nebulizer to it in order for the nebulizer to perform intranasal administration. Close proximity between the livestock animal and the handler often creates physical dangers to both the handler and the animal. A stated purpose of the claimed present invention is to greatly reduce the dangers associated with the close proximity required for injections and intranasal administration by claiming an exterior muzzle application that can be performed at a safer distance using the claimed application method. Livestock animals generally resist being restrained and/or having

foreign objects fixed to their heads and would undoubtedly put up resistance to treatment with a nebulizer. Teaching the use of a nebulizer that inherently requires close proximate contact between the handler and the livestock creates one of the deficiencies in the prior art that the present invention was created to overcome. The use of an administration method that provides close proximate contact between the handler and the livestock teaches away from the present invention. Accordingly, Dowling teaches away from the claimed limitations of the present invention by teaching and suggesting intranasal administration of the vaccine that requires close proximity to administer prophylactic compositions.

3. Gallili does not teach, suggest, or motivate a person skilled in the art to use a post-application identifier and Gallili teaches away from applying an effective dose of prophylactic directly to the muzzle.

The Examiner is directed to Section C(3) and C(4) above for Applicant's arguments regarding Gallili's teaching, suggestion and motivation as applied to the present invention.

4. There is no rationale, articulation, or reasoned basis presented to explain how the present invention is the expected result when a person of ordinary skill in the art combines the teachings of Dowling and Gallili.

There is no teaching, suggestion, motivation, or official notice of knowledge in the art that would create the reasonable expectation that the present invention would result from the combination of Chu and Gallili; therefore, the required components of a prima facie case of obviousness have not been satisfied.

The combination of the cited references to Dowling and Gallili would result in a method of administering vaccine to a livestock animal using a nebulizer positioned over the nose and mouth of the animal that provides a vaccine solution as a mist that is administered intranasal to

the livestock animal into the livestock animal's respiratory system wherein the vaccine solution is created by dissolving a colored tablet containing the vaccine in water and, prior to placing the tablet in solution, the type of vaccine was identified in part by the color of the tablet. This combination of the cited references alone is most definitely does not meet the claimed limitations of the present invention of directly applying an effective dose of a prophylactic composition directly to the muzzle of the livestock animal, wherein the livestock animal will distribute the effective dose of the composition directly to the oral and nasal mucosa, and the prophylactic composition contains a prophylactic agent and a post-application identifier. Therefore, the cited prior art elements must provide a person skilled in the art the teaching, suggestion or motivation to modify the references in order to reasonably expect the present invention. Dowling or Gallili do not provide such teaching, suggestion or motivation; therefore, the present invention is not a reasonably expected result of the combination of Dowling and Gallili.

Accordingly, Dowling and Gallili, individually and in combination, fail to teach or suggest the combination asserted by the Examiner. Further, neither of the references teaches nor suggests all of the elements of independent claim 27 and no resultant method could have been created from these references that would meet the limitations of these claims. Dowling does not teach direct application of an effective dose of a prophylactic composition to the muzzle of an animal or that the effective dose of the prophylactic composition will be delivered to the nasal or oral mucosa by the animal's tongue. In fact, Dowling teaches away from direct application to the muzzle by disclosing intranasal administration that requires close proximity and head restraint. Moreover, a tablet only includes sufficient colorant in the vaccine tablet to identify the vaccine by color prior to application and does not teach, suggest, or motivate a person skilled in the art to use the colorant disclosed by Gallili to be a post-application identifier. Gallili does not

suggest that the concentration of dye in the diluted vaccine solution is sufficient to be used as a post-application identifier or teach, suggest or motivate a person of ordinary skill in the art to use colorant as such. In actuality, the presence of the colorant when added to a nebulized vaccine solution would have little or no visibility for pre- or post administration identification. Therefore, one of ordinary skill in the art would not have arrived at Applicant's claimed invention because Applicant's invention would not be an expected result of the combination of these references since both Dowling and Gallili, individually and in combination, fail to meet all the claimed limitations of the present invention. Accordingly, Applicant's independent claim 27 and the claims depending therefrom are nonobvious.

F. Rejection of Claim 23 over Dowling in view of Gallili, further in view of Emery et al.

Claim 23 was rejected under 35 U.S.C. 103(a) as being unpatentable over Dowling et al. in view of Gallili et al., further in view of Emery et al. US 5,906,826. Per the arguments presented above in Section E, the combination of Dowling and Gallili does not establish a prima facie case of obviousness for independent claim 27 or the claims depending therefrom. In addition, Dowling, Gallili, and Emery, individually or in combination, do not teach, suggest, or motivate the combination asserted in the Office Action. Emery may teach additives to prophylactic composition; however, Emery does not teach one skilled in the art to directly apply an effective dose of such composition to the muzzle of a livestock animal wherein the animal distributes the effective dose to the animal's oral and nasal mucosa with its tongue. Emery contains no suggestion or motivation to alter the disclosed composition for such application, nor would a person of ordinary skill in the art expect the present invention when considering

Dowling, Gallili, or Emery whether alone or in combination.

G. Rejection of Claims 25 and 34 over Dowling in view of Gallili, further in view of Demello et al.

Claims 25 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Dowling et al. in view of Gallili et al., further in view of Demello et al. US 5,846,830. Per the arguments presented above in Section E, the combination of Dowling and Gallili does not establish a prima facie case of obviousness for independent claim 27 or the claims depending therefrom. In addition to the previous argument regarding the combination of Dowling and Gallili, the Applicant directs the Examiner to Section D for Applicant's arguments regarding the failure of Demello to teach, suggest or motivate a UV post-application identifier. Further, Demello does not teach directly applying an effective dose of a prophylactic composition to the muzzle of a livestock animal wherein the animal distributes the effective dose to the animal's oral and nasal mucosa with its tongue. Thus, Dowling, Gallili, and Demello, alone or in combination, create no reasonable expectation of the claimed limitations of the present invention when the teachings, suggestions and motivations of Demello are added to the combination of Dowling and Gallili. Accordingly, Applicant's claim 34 is nonobvious.

H. Rejection of Claims 17, 22, 25, 26, 27, 32, 34 and 35 over Squires in view of Reynolds.

Claims 17, 22, 25, 26, 27, 32, 34 and 35 were rejected under 35 U.S.C. 103(a) as being unpatentable over Squires et al., US 6,350,784 B1, in view of Reynolds et al., US 5,753,244.

For the following reasons, Applicant respectfully requests reconsideration and withdrawal of these rejections.

The Office Action asserts that "Squires et al teaches a method of treating livestock e.g. a horse to achieve positive effect on the health of the horse comprising applying topically a veterinary prophylactic compound (also a veterinary prophylactic composition since it is administered to a horse) comprising an effective dose of viral inhibitors directly to a muzzle of said horse (see treatment of wart on muzzle of said horse, column 28 example 14)." The Office Action then asserts that "[s]ince the viral inhibitor is applied to the muzzle of said horse, said horse distributes the viral inhibitor composition into the oral and/or nasal cavity when it engages in inherent licking of its muzzle with its tongue."

The Office Action further observes that "Reynolds et al teaches skin treatment products such as a drug that comprises a light visible dye that changes from one color to another color (light visible dye) or colored dyes that become invisible or colorless after application to the skin (non-visible dye) which insures uniform application to the skin for complete coverage of a desired area." Further, the Office Action concludes that it "would have been prima facie obvious to one of ordinary skill in the art at the time the instant invention was made to add any of the dyes of Reynolds et al to the composition of Squires et al because Reynolds et al teaches that such dyes ensure uniform application to the skin for complete coverage of a desired area, thus resulting in the instant invention with a reasonable expectation of success." Applicant respectfully traverses the assertion that the Squires and Reynolds references, alone or in combination, teach or suggest all of Applicant's claim limitations or that the claimed limitations of the present invention are expected when Squires and Reynolds are combined. Applicant's claimed invention, directed to a method of administration of the prophylactic compositions to

livestock animals is not rendered obvious by the combination of Squires and Reynolds for the reasons discussed hereinbelow.

1. Squires does not teach, suggest or motivate the use of a prophylactic composition in veterinary applications.

Squires does not teach, suggest, or motivate the claimed limitations of the present invention as asserted in the Office Action to meet a prima facie showing of obviousness. Squires teaches topically applying an effective dose of a medical compound to a virus-caused wart located on a horse's muzzle in Example 14 located in column 28. The medical compound taught in Squires is not a veterinary prophylactic compound and is only a topical viral inhibiter for the treatment of viral related skin conditions.

Squires disclosure of a medical treatment is focused on inhibiting the HIV virus and other human viruses; however, the medical treatment and medicine "can also be useful for veterinary purposes for treating viral and bacterial infections and infectious diseases in animals" such as livestock animals (column 6, lines 20-28). This teaching necessarily means that Squires' medical treatment and medicine are used in veterinary cases only for treatment after an animal shows symptoms of a viral or bacterial infections or infectious disease. In fact, the only veterinary example of Squires invention, Example 14, teaches the topical treatment of a papilloma virus-caused wart on the muzzle of a two year old gelded thoroughbred horse—a pre-existing, virus-caused skin condition.

Squires' veterinary medical treatment and medicine are only topical treatments for infections caused by virus or bacteria and are not prophylactic compositions. Prophylactic is defined as "acting to defend against or prevent something, especially disease; protective." American Heritage Dictionary, 4th ed. Squires teaches that the composition is used to solely

treat viral and bacterial infections and infectious diseases in veterinary applications and not to prevent the same. Further, by specifically disclosing a prophylactic use of Squires' composition for preventing the spread of HIV in humans (col. 5, lines 59-65) and not disclosing the same preventative use in animals, Squires teaches away from using Squires' composition as prophylactic in veterinary applications by purposefully omitting this use in the disclosure. Therefore, Squire does not teach, suggest or motivate the use of a prophylactic composition that can be used in animals.

2. Squires does not teach, suggest or motivate the direct application of an effective dose of a prophylactic composition to the muzzle of an animal wherein said effective dose is delivered to the oral and nasal mucosa of said animal.

Squires' disclosed veterinary composition is, as noted by the Office Action, a topical medicament. The definition of topical, as set forth for medical purposes, is "of or applied to a localized area of the body or to the surface of a body part." American Heritage Dictionary, 4th ed. Topical medicaments are inherently meant to be effective and treat only the area to which they are applied. Thus, Squires' disclosure cannot teach both limitations of the present invention—the application of an effective dose of a prophylactic compound to the muzzle of the animal, and the distribution of an effective dose to the oral or nasal mucosa using the animal's tongue. Example 14 of Squires involves treating a papilloma virus-caused wart on the muzzle of a two year old gelded thoroughbred horse by applying the composition on the wart twice a day. Squires teaches applying its composition to the muzzle of a horse only because the wart being treated was located on the muzzle. Had the wart been located on the leg of the horse, Squires' method would require applying the composition on the horse's leg. The therapeutic effect of Squires' method requires an effective dose to be applied and maintain contact with the infected

area. This requirement is mutually exclusive with distributing the effective dose to and absorbing the effective dose through the animal's oral or nasal mucosa.

Moreover, once an effective dose of the topical composition is applied, it becomes ineffective as soon as it is removed or wiped off the infected area. As soon as a horse licks its muzzle, distributing the effective dose of Squire's composition on the muzzle to the nasal or oral mucosa—a conclusion fundamental to this objection—results in Squires' topical dose to treat the infection on the muzzle being no longer effective. Therefore, Squire's topical composition teaches away from the present invention because applying a topical treatment is incongruous with the method of administering a prophylactic treatment in the present invention wherein the dose is effective when applied to the muzzle and the effective dose is distributed to the oral and nasal mucosa via the animal's tongue. The effective dose is only such because it is absorbed by the animal through the oral and nasal mucosa. Moreover, there is no reliance on the tongue as an agent of distribution in either Squires or Reynolds. Further, a topical composition is not usually intended to be ingested and may actually be harmful to the animal, which is in direct conflict with achieving a positive affect on the health of an animal. A topical viral inhibitor is not a prophylactic compound and the topical nature of the treatment in Squires necessarily disqualifies it from being cited to teach, suggest or motivate a person skilled in the art to apply an effective dose of a prophylactic compound to the muzzle of an animal and having the dose remain effective when the animal distributes the composition to the animal's oral or nasal mucosa with its tongue.

3. Reynolds does not teach, suggest, or motivate a person skilled in the art to use a UV or other non-visible dye as a post-identification identifier.

The Office Action sets forth that "Reynolds et al teaches skin treatment products such as

a drug that comprises . . . colored dyes that become invisible or colorless after application to the skin (non-visible dye) which insures uniform application to the skin for complete coverage of a desired area." The disclosure of a dye that becomes invisible is not a disclosure of a UV or other non-visible dye. The distinction is that the non-visible dye can be observed using a well known viewing lens, light or machine, whereas, a disappearing dye can no longer be seen in any capacity. Therefore, the disappearing dye in Reynolds does not function as a post-application identifier because the dye actually disappears thereby rendering it useless as post-application identifier. Therefore, Reynolds does not disclose the limitation of claim 34, nor does Reynolds teach, suggest or motivate a person skilled in the art to implement a UV or other non-visible dye.

4. There is no rationale, articulation, or reasoned basis explaining how the present invention is an expected result of a person of ordinary skill in the art combining Squires and Reynolds.

The combination of Squires and Reynolds results in a topical veterinary compound that is used to treat virus-caused infections after an animal shows symptoms of a viral or bacterial infection or infectious disease and has a light-visible dye that changes color when it is exposed to air, light, heat or the skin allowing the person applying the compound to see where the compound has been applied. The method taught by the disclosures of the combined reference is ineffectual in delivering an effective dose of a prophylactic compound to the nasal and oral mucosa as claimed in the present invention. The compound is only applied to the muzzle of an animal if a skin infection or irritation (i.e. wart of example 14) is present on the muzzle. Squires and Reynolds do not teach or suggest to a person skilled in the art that Squires' composition is also effectual if applied to the muzzle and then delivered to the oral and nasal mucosa. As set forth previously, delivering a topical medicament to the oral or nasal mucosa may actually harm

the animal which is indirect opposition to the purpose of the present invention.

The compound resulting from the cited combination of Squires and Reynolds is a topical compound and that is effective in veterinary applications to topically treat viral and bacterial infections and infectious diseases in animals. Therefore, if the infection or irritated area is on an animal's muzzle, the Squires and Reynolds topical compound would no longer be effective in treating the infected or irritated area on the muzzle when the animal distributes the compound to the animal's oral or nasal mucosa. Further, the presence of the light visible dye in Reynolds would erroneously indicate that the animal has been treated with an effective dose after the compound has been removed from the muzzle and distributed to the oral and nasal mucosa. Alternatively, the dye of Reynolds would be ineffective as an indicator when the animal licks it off. The present invention claims a light visible die as a post-application identifier that is intended to be visible after an animal distributes the effective dose of the prophylactic compound to the oral and nasal mucosa. Reynolds provides no teaching, suggestion or motivation to provide dye that will remain visible if the compound is licked off or washed off.

Accordingly, Squires and Reynolds, individually and in combination, fail to teach or suggest the combination asserted in the Office Action. Further, neither of the references teaches nor suggests all of the elements of independent Claim 27 and no resultant method could have been created from these references that would meet the limitations of the present claims. Squires does not teach the use of a veterinary prophylactic compound. Squires does not teach that the effective dose of the prophylactic composition is required to be delivered to the nasal or oral mucosa by the animal's tongue. In fact, Squires topical medicament teaches away from having the effective dose of the prophylactic compound delivered to the nasal and oral mucosa. Moreover, Reynolds also fails to teach claimed limitation of a UV or other non-visible dye.

Therefore, one of ordinary skill in the art would not have arrived at Applicant's claimed invention because Applicant's invention would not be an expected result of the combination of these references since both references, individually and in combination, fail to meet all the limitations of the subject claims. Accordingly, Applicant's independent claim 27 and the claims depending therefrom are nonobvious.

I. Rejection of Claims 18-20, 23-24, and 28-30 over Squires in view of Reynolds further in view of Callaghan.

Claims 18-20, 23-24 and 28-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over Squires et al., in view of Reynolds et al., further in view of Callaghan, US 6,410,062. The Office Action states "Callaghan teaches a topical formulation for treating a skin disorder." Regardless of the multitude of properties that are disclosed by Callaghan, Callaghan teaches a topical formulation. Per the arguments above in Section H, a topical formulation as disclosed in Callaghan and in Squires fail to teach, suggest, motivate or create a reasonable expectation of the present invention when combined with Reynolds. Callaghan does not make up the shortcomings of the topical treatment of Squires and Reynolds in making a prima facie showing of obviousness of the present invention. Accordingly, Applicant's independent claim 27 and all the claims depending therefrom are nonobvious.

IV. CONCLUSION

Applicant respectfully submits the claims and the application are in condition for allowance and such is courteously solicited. If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be

taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicant's undersigned attorney in this regard. Should any fees be necessitated by this response, the Commissioner is hereby authorized to deduct such fees from Deposit Account No. 11-0160.

Respectfully submitted,

Date: 8-10-2009

Robert J. Bowman
Reg. No. 62,558
Husch Blackwell Sanders LLP
4801 Main St., Suite 1000
Kansas City, MO 64112
816-983-8000
ATTORNEYS FOR APPLICANT